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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,803	02/25/2001	Bruno Donatini	GEI-089	7157

20311 7590 08/13/2002

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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 08/13/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/069,803

Applicant(s)

Donatini

Examiner

Michele Flood

Art Unit

1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 25, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2 20) ☐ Other: _____

Art Unit: 1651

DETAILED ACTION

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The invention concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Information Disclosure Statement

The information disclosure statement filed on October 25, 2001 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. In the

Art Unit: 1651

instant case, foreign patent document (DE 4141889) has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regard to Claim 1, line 1, the plural recitation of the phrase "Fungi-based pharmaceutical and/or dietary compositions" in the preamble is awkward and confusing because it appears that more than one invention is being claimed. It is suggested that Applicant delete the above mentioned phrase and replace it with A pharmaceutical composition to direct the claimed invention to a singular invention.

Claims 1-13 recite the phrases, "characterized in that that" and "characterized in that". Although the phrases do not raise to the level of indefiniteness and it appears that the first occurrence of the phrases is a typographical error, it is suggested to replace the abovementioned phrases with wherein to provide consistency in the claim language.

Claim 1 is rendered vague and indefinite by the phrase "combined or mixed with a diluting agent or a non-toxic vehicle" because it is unclear as to what is combined or mixed with

Art Unit: 1651

a diluting agent or a non-toxic vehicle. For instance, are the claimed ingredients combined or mixed with the claimed compositions or the contaminants? The lack of clarity renders the claim ambiguous.

Regarding claims 1 and 12, the phrase "such as" renders the claims indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The metes and bounds of Claim 4 are rendered vague and indefinite by the phrase "the chitosan is formed from a mixture of acid chitosan and basic chitosan" because it is unclear as to the subject matter Applicant intends to direct the invention. For instance, in what way is the claimed chitosan "formed from a mixture of acid chitosan and basic chitosan"; and, in what way do the properties of a chitosan "formed from a mixture of acid chitosan and basic chitosan" differ from any other chitosan, such as an acid chitosan or a basic chitosan? Is the chitosan "formed from a mixture of acid chitosan and basic chitosan" a neutral chitosan or a polyionic chitosan? Or, does Applicant direct the invention to another embodiment of the invention, wherein more than one type of chitosan comprises the claimed composition, e.g., a composition comprising both an acidic chitosan and a basic chitosan? The lack of clarity makes the claim very ambiguous and confusing.

Claim 5 recites the limitation "the chitosan in acid form" in line 2. The claim lacks clear antecedent basis for this limitation. Applicant may overcome the rejection by replacing the limitation with acid chitosan.

Art Unit: 1651

Claim 6 recites the limitation "or cationic form" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "to the chitin" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claims 6 and 13 appear to claim a Markush group without the proper use of the Markush format. Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B, and C". See *Ex parte Markush*, 1925 C. D. 126 (Comm'r Pat. 1925).

Claim 7 recites the limitation "the chitin" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 is rendered vague and indefinite by the phrase "chitosan contents range" because the phrase is not in proper grammatical form, which makes the subject matter to which Applicant intends to direct the claimed invention unclear. It would appear that Applicant may overcome the rejection by replacing the phrase with content of the chitosan ranges.

Claim 11 recites the limitation "the total mass" in line 3. The claim lacks clear antecedent basis for this limitation. For instance, it is unclear as to what "the total mass" refers to, i.e., the total mass of what?

Art Unit: 1651

Claim 11 recites the limitation "the chitosan contents" in 2. There is insufficient antecedent basis for this limitation in the claim.

Regarding Claim 13, there are apparent typographical errors. Applicant may overcome the rejection by replacing "Armillara Mellea" with Armillaria mellea; by replacing "Agaricus bisorus" with Agaricus bisporus; by replacing "Hericim" with Hericium; by replacing "Phellinus linateus" with Phellinus linteus; by replacing "Tremela" with Tremella; and by replacing "Volvaria" with Volvariella. Accordingly, page 7, lines 21-25, should be amended to reflect the changes.

Claim 14 provides for the use of the claim designated composition, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 14 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Regarding claim 14, the phrase "and the like" renders the claim indefinite because the claim includes elements not actually disclosed (those encompassed by "or the like"), thereby rendering the scope of the claim unascertainable.

Art Unit: 1651

Claims 1-14 are generally narrative and indefinite, failing to conform with current U.S. practice. They appear to be a literal translation into English from a foreign document and are replete with grammatical and idiomatic errors. For example, Claim 14 recites the idiomatic phrase "with a view to the achievement of". It is suggested that the phrase be deleted from the claim language to conform with standard U.S. practice.

Although 14 has been rejected under 35 U.S.C. 101 and 35 U.S.C. 112, second paragraph, (as set forth immediately above), the claim has been examined on the merits to expedite prosecution of the application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b).

Art Unit: 1651

Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 2, 5-7, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Tanaka et al. (JP 08-131120, AA3 or W). Translation of the foreign document provided herein (W).

Applicant claims a fungi-based pharmaceutical and/or dietary compositions, wherein the compositions contain one or more fungi or parts of edible fungi having therapeutic properties and chitosan as a chelating agent of contaminants, and a method of use thereof. Applicant further claims a composition wherein the chitosan is an acid chitosan having a pH less than 6 and is obtained by addition to chitin an organic acid selected from the group consisting of acetic acid, lactic acid, succinic acid, tartaric acid, ascorbic acid, citric acid, glutamic acid, methanesulphonic acid and ethanesulphonic acid.

Tanaka teaches a health food noodle composition comprising *Ganoderma lucidum*, powder of fungi, and chitosan lactic acid solution, which is used for cleaning of blood, stimulation of bloodstream, prevention of sleepiness, liver disorders and cancer treatments. On page 2 of the translation, lines 4-5, Tanaka teaches a mixture of *Ganoderma lucidum* and wild-rice powder having cancer inhibiting activity.

The prior art teaches a pharmaceutical composition comprising the claimed ingredients of fungi and chitosan. The prior art is silent on the claimed functional effect of chitosan as a chelating agent and the chitosan having a pH less than 6. However, Tanaka does teach that the

Art Unit: 1651

composition comprises a chitosan lactic acid solution; and, therefore the claimed pH range of the chitosan comprising the composition taught by Tanaka must be inherent to the referenced composition. Moreover, as the referenced composition comprises the claimed ingredients, the claimed functional properties of the disclosed composition must be inherent to the referenced composition, since the prior art teaches that the composition comprises an edible therapeutic fungi and a chitosan.

The reference anticipates the claimed subject matter.

Claims 1, 3, 8, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Takenaka et al. (JP 09-149774, AA5 or X). Translation of the foreign document provided herein (X).

Applicant further claims a composition wherein the chitosan is a basic chitosan; wherein the basic chitosan has a pH of between 7 and 12; and, wherein the fungi or the parts of the fungi are used in fresh form or in the form of a dry extract.

Takenaka teaches a composition comprising an extract of mushroom, *Agaricus blazei* Murr, and chitosan, which is an anti-oxidation dietary health food product. The mushroom extract is taught as a polysaccharide having immunological enhancing and cholesterol lowering properties. The composition taught by Takenaka is prepared by admixing an extract of microalga with hot water to chitosan, agar and mushroom extract at a pH of 8.

Art Unit: 1651

The prior art teaches a pharmaceutical composition comprising the claimed ingredients of fungi and chitosan. The prior art is silent on the claimed functional effect of chitosan as a chelating agent. However, as the referenced composition comprises the claimed ingredients, the claimed functional property must be inherent to the referenced composition, since the prior art teaches that the composition comprises an edible therapeutic fungi and a chitosan.

The reference anticipates the claimed subject matter.

Claims 1 and 12-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Maeda et al. (JP 10-276718, AA4 or V1). Translation provided herein (V1).

Applicant's claimed invention was set forth above.

Maeda teaches a health food product comprising *Lentinus edodes* (shiitake mushrooms), *Ganoderma*, and chitosan. The ingredients are combined, dried and pulverized to obtain a powder which is used as a food additive or a tablet by those having difficulty maintaining a balanced diet, e.g., bachelors and students.

The prior art teaches a pharmaceutical composition comprising the claimed ingredients of fungi and chitosan. The prior art is silent on the claimed functional effect of chitosan as a chelating agent. However, as the referenced composition comprises the claimed ingredients, the claimed functional property must be inherent to the referenced composition, since the prior art teaches that the composition comprises an edible therapeutic fungi and a chitosan.

The reference anticipates the claimed subject matter.

Art Unit: 1651

Claims 1, 3 and 11-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato (JP 08-322506, AA2 or U1). Translation of the foreign document provided herein (U1).

Applicant's claimed invention was set forth above.

Kato teaches a health food pharmaceutical comprising 60-40 wt. % of the edible mushroom, *Grifola frondosa* (maitake mushrooms), and 40-60 wt. % of chitosan. The *Grifola frondosa* used in the preparation of the composition is preferably a dried product, but may also be used fresh. The composition taught by Kato is used for the treatment of hyperlipemia, weight-loss and for improving immunological function. Kato further teaches the individual therapeutic effects of *Grifola frondosa* and chitosan. For example. In [0003], Kato teaches that chitosan as a food additive promotes the excretion of chlorine present in food (when it is ingested). In [0015], Kato teaches that the chitosan used in the method of preparing his composition is used mainly as a heavy metal adsorbent and contaminant remover in various industries, such as a cation system (thus, a basic chitosan) activated sludge condensation material or recovery of protein in waste fluid; but, as a biocompatible material, Kato teaches that the chitosan of his invention physiologically removes cholesterol and other impurities from the body (when it is ingested). In [0016], Kato teaches that the edible mushrooms contain numerous elemental nutrients. A method of administering the referenced composition is taught in [0019].

The prior art teaches a pharmaceutical composition comprising the claimed ingredients of fungi and chitosan. Although Kato does not expressly teach the chitosan comprising the referenced composition as a chelating agent, the claimed functional property is inherent to the

Art Unit: 1651

composition taught by Kato because the ingredients, the amounts of the ingredients, and the beneficial functional health effect of the composition taught by Kato are one and the same as instantly claimed by Applicant.

The reference anticipates the claimed subject matter.

Claims 1, 2, 6, 7, 12 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatanaka (JP 05316967, N).

Hatanaka teaches a dietary composition, which is prepared by mixing an edible acid (e.g., lactic acid) and an extract of *Monascus purpureus* (an edible fungi, a yeast) into water, dissolving chitosan into the liquid mixture and drying the solution.

The prior art teaches a pharmaceutical composition comprising the claimed ingredients of fungi and chitosan. The prior art is silent on the claimed functional effect of chitosan as a chelating agent. However, as the referenced composition comprises the claimed ingredients, the claimed functional property must be inherent to the referenced composition, since the prior art teaches that the composition comprises an edible therapeutic fungi and a chitosan.

The reference anticipates the claimed subject matter.

Art Unit: 1651

Claims 1, 3, 9, 10 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Zaveri (A).

Applicant further claims a composition according to claim 1 wherein the chitosan is a basic chitosan, and wherein the basic chitosan is an alkyl carboxamide.

In Column 3 lines 51-67 to Column 4, lines 1-12, Zaveri teaches an anti-inflammatory pharmaceutical composition comprising a yeast extract and chitosan succinamide. See claim 13.

The prior art teaches a pharmaceutical composition comprising the claimed ingredients of fungi and chitosan. The prior art is silent on the claimed functional effect of chitosan as a chelating agent. However, as the referenced composition comprises the claimed ingredients, the claimed functional property must be inherent to the referenced composition, since the prior art teaches that the composition comprises an edible therapeutic fungi and a chitosan.

The reference anticipates the claimed subject matter.

Claims 1, 2, 5, 6, 12 and 14 are rejected under 35 U.S.C. 102(a) as being anticipated by Tianwei et al. (U).

Applicant's claimed invention was set forth above.

Tianwei teaches a composition comprising a mycelium of penicillin chrysogenum mycelium which contains large amounts of chitosan, on page 169, line 24-26. By adding either hydrochloric acid or sodium hydroxide to a metal ion concentration comprising an amount of

Art Unit: 1651

dried biomass of penicillin, Tianwei determined the bioadsorption capacity of the fungi (see Figure 2 on page 171 and Table 1 on page 172).

It is noted that the reference does not teach that the composition can be used in the manner instantly claimed, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Applicant is asked to review *In re Hack*, 245 F.2d 246, 248, 114 USPQ 161, 163 (CCPA 1957). "When the claim recites using an old composition or structure and the "use" is directed to a result or property of that composition or structure, then the claim is anticipated" (MPEP 2100 pp. 2113).

The reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tanaka et al.

Art Unit: 1651

(AA3) and/or Hatanaka (N) and Takenaka et al. (AA5) in view of Zaveri (A) and/or Kato (JP 08-322506, AA2), and further in view of Aoyangi (O) and Nishimura et al. (V).

Applicant's claimed invention was set forth above. Applicant further claims a compositions according to claim 1, wherein the chitosan is formed from a mixture of acid chitosan and basic chitosan. The claims have been read as comprising a mixture of an acid chitosan and basic chitosan (see USC 112, second paragraph, set forth *supra*).

Tanaka teaches a health food composition comprising *Ganoderma lucidum*, powder of fungi and chitosan lactic acid solution, which is used for cleaning of blood, stimulation of bloodstream, prevention of sleepiness, liver disorders and cancer treatments. Hatanaka teaches a dietary composition, which is prepared by mixing an edible acid (e.g., lactic acid) and an extract of *Monascus purpureus* into water, dissolving chitosan into the liquid mixture and drying the solution.

The teachings of Tanaka and Hatanaka are set forth above. Neither Tanaka nor Hatanaka teach fungi-based pharmaceutical and/or dietary compositions wherein the chitosan is formed from a mixture of acid chitosan and basic chitosan. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add a basic chitosan to the pharmaceutical and/or dietary composition(s) taught by Tanaka and/or Hatanaka to provide the claimed pharmaceutical and/or dietary composition(s) because Takenaka and Zaveri teach fungi-based pharmaceutical and/or dietary compositions comprising basic chitosans. Firstly, Takenaka teaches a composition comprising an extract of mushroom, *Agaricus blazei* Murr and chitosan, as

Art Unit: 1651

an anti-oxidation dietary health food product. The mushroom extract is taught as a polysaccharide having immunological enhancing and cholesterol lowering properties. The composition taught by Takenaka is prepared by admixing an extract of microalga with hot water to chitosan, agar and mushroom extract at a pH of 8. Secondly, in Column 3, lines 51-67 to Column 4, lines 1-12, Zaveri teaches a pharmaceutical composition comprising a yeast extract and chitosan succinamide. See claim 13. Thirdly, Kato teaches a health food pharmaceutical comprising 60-40 wt. % of the edible mushroom, *Grifola frondosa* (maitake mushrooms), and 40-60 wt. % of a chitosan. The *Grifola frondosa* used in the preparation of the composition is preferably a dried product, but may also be used fresh. The composition taught by Kato is used for the treatment of hyperlipemia, weight-loss and for improving immunological function. Kato further teaches the individual therapeutic effects of *Grifola frondosa* and chitosan. For example. In [0003], Kato teaches that chitosan as a food additive promotes the excretion of chlorine present in food (when it is ingested). In [0015], Kato teaches that the chitosan used in his invention is used mainly as a heavy metal adsorbent and contaminant remover in various industries, such as a cation system (thus, a basic chitosan) activated sludge condensation material or recovery of protein in waste fluid; but, as a biocompatible material, Kato teaches that the chitosan of his invention physiologically removes cholesterol and other impurities from the body (when it is ingested). In [0016], Kato teaches that the edible mushrooms contain numerous elemental nutrients. A method of administering the referenced composition is taught in [0019]. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention

Art Unit: 1651

was made to add the fungi-based pharmaceuticals comprising acidic chitosan taught by Tanaka and/or Hatanaka to the fungi-based pharmaceuticals comprising basic chitosan taught by Takenaka, and/or Zaveri, and/or Kato in the making of the claimed composition because it is well known that its *prima facie* obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. *In re Pinten*, 459 F. 2d 1053, 173 USPQ 801 (CCPA 1972); *In re Susi*, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the claimed ingredients taught by the prior art references because each of the claimed ingredients were each individually known for their beneficial health-promoting effects.

With regard to the claim functional effect of chitosan as a chelating agent, it would have been obvious to one of ordinary skill in the art to add chitosan in the making of the claimed pharmaceutical composition, wherein the chitosan exhibited chelating activity because at the time the invention was made the functional effect of chitosan as having beneficial therapeutic effects and chelating properties was well established, as evidenced by the teachings of Aoyanagi and Nishimura. Firstly, Aoyanagi (JP 09075723) teaches an agent comprising a basic chitosan that adsorbs and removes harmful contaminants deposited on or contained in food, or present in a

Art Unit: 1651

digestive system, and a method of use thereof comprising bringing the agent in direct contact with the food. The agent is prepared by dispersing an activated carbon in a gel dispersion medium comprising chitosan-oxalate gel. See [0018] of the translation, wherein Aoyanagi teaches that the referenced composition is used to as an adsorption-treatment agent to remove food contaminants from food products, e.g., food additives, feed additives, heavy metals, agricultural chemicals, etc. Aoyanagi further teaches that the agent removes excess nutrients present in a digestive system and the intermediate metabolite of alcohol that forms in the digestive system after drinking alcohol. Secondly, Nishimura teaches administering chitosan for the removal of ingested radiostrontium. At the time the invention was made, one of ordinary skill in the art would have been motivated and one of ordinary skill in the art would have had a reasonable expectation of success to add a chitosan, such as the chitosans taught by either Aoyanagi or Nishimura, to the prior art fungi-based pharmaceuticals comprising chitosan to provide the claimed invention because Aoyanagi teaches that the chitosan removes excess nutrients present in a digestive system, removes harmful contaminants present in foods, and removes the intermediate metabolite of alcohol that forms in the digestive system after drinking alcohol because both Aoyanagi and Nishimura teaches that chitosan reduces the bioavailability of undesirable compounds present in food in the digestive system. Thus, the claimed invention is no more than the combining of well known ingredients used in well known methods for their beneficial health promoting effects because at the time the invention was made the functional and therapeutic beneficial effect of chitosan as a chelating agent in the removal and/or absorption of

Art Unit: 1651

contaminants was well established in the art, as evidenced by the teachings of Aoyanagi and Nishimura; and the functional and therapeutic beneficial effect of fungi-based pharmaceuticals comprising chitosan in the promotion of health was well known in the art, as evidenced by the teachings of Tanaka, Hatanaka, Takenaka, Zaveri, and Kato.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claims 1-5 and 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kato (JP 08-322506, AA2) in view of Angerer et al. (B).

Applicant's claimed invention was set forth above.

The teachings of Kato were set forth above.

Kato does not teach a pharmaceutical composition further comprising an acid chitosan. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add an acid chitosan to the composition comprising fungi and a basic chitosan taught by Kato to provide the claimed pharmaceutical because Angerer teaches a composition comprising an acid chitosan that has beneficial health promoting effects. For instance, Angerer teaches a water-soluble acid-chitosan complex which is administered to animals for the prevention of fat digestion, in Column 1, lines 9-14. In Column 2, lines 26-29, Angerer teaches administering the acid-chitosan to reduce the release of triglycerides into the blood stream of animals. See Column 4, line 51 to Column 5, lines 1-36, also. The acid-chitosan is prepared by

Art Unit: 1651

mixing chitosan and betaine hydrochloride, and has a pH of 3 (see Column 6, lines 1-10). At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the acid-chitosan taught by Angerer to the pharmaceutical composition taught by Kato to provide the claimed pharmaceutical composition(s) because Angerer teaches that the referenced composition is easy to prepare, has good shelf stability, and improves the overall health of animals. Moreover, it would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman*, 1943 C.D. 518. Applicants invention may be predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him.

Art Unit: 1651

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

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August 9, 2002